2018 Revised Common Rule for Human Subjects Research

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Summary of Revisions

Compliance Date

January 2018. The new regs leave it up to the institution to decide whether they should be applied to pre-2018 active protocols.

Definition of Research

Remains the same as previous rule but includes examples of activities that are not considered research:

- Journalistic and scholarly activities -- includes oral history, journalism, literary criticism, legal research, historical scholarship, and collection and use of data that focuses on specific individuals.
- Public health surveillance activities.
- Criminal investigations.
- National security.

Exempt Research

- Adds 3 new categories (benign interventions under certain conditions, storage and maintenance of identifiable secondary data and biospecimens, use of identifiable secondary data and biospecimens); omits 1 current category (public officials).

- Expands and clarifies existing categories, including clarifications on which exemptions can be applied to subparts B (pregnant women), C (prisoners), and D (children).

- Introduces concept of "limited IRB review" for certain categories. Limited IRB review only evaluates privacy, confidentiality, and consent – can be conducted under expedited review or administrative review by a qualified staff member.

- Introduces concept of "broad consent" for storage, maintenance, and use of identifiable private information and identifiable biospecimens in secondary research such as that covered by exemption categories 7 and 8. Broad consent may not be used for any other research except secondary research, which involves identifiable private information or identifiable biospecimens that are collected orginally for another research activity or for a non-resarch activity.

Refer to the Table of Exemption Categories for a list of the exemption categories under the revised rule, info on how the exemptions apply to the subparts under the revised common rule, and my recommendations on how consent should be applied under SJSU policy:
http://www.sjsu.edu/research/docs/2018-Table-Exemption-Categories.pdf

Continuing Review

Omits requirement for continuing review of research that qualified for expedited review (i.e., approval does not have an expiration date but PIs must continue to inform IRB about modifications); otherwise IRBs must provide and document justification for requiring a continuing review of each protocol.

Single IRB Mandate

• Only one IRB review for cooperative research that involves multiple study sites – to be determined either by the federal sponsor of the research or by consensus between institutions.

• Reliance agreements for cooperative research should list the allocated responsibilities of each institution.

Consent

• Requirement that consent forms include essential info first (e.g., elements of informed consent) and are designed to facilitate understanding.

• Addition to basic elements of informed consent: whether or not research data involving identifiable secondary data or biospecimens will be shared for use in future research even if identifiers are removed.

• Expanded additional elements of informed consent (used when applicable) to include whether biospecimens will be used for commercial profit and whether subject will share in that profit.

• No consent required for access to secondary data from records or directly from subjects for the purposes of recruitment, screening, and determining eligibility for participation as long as confidentiality and privacy safegaurds are in place.

• Outlines conditions under which broad consent may be used -- only for secondary research involving identifiable private information or identifiable biospecimens.

• Outlines the elements of broad consent – are more extensive than typical consent.

• Waivers of informed consent and documentation of informed consent under standard IRB review remain the same.

• Revision of terminology "mental disability" to "individuals with impaired decision making ability"

• Expansion of the concept of vulnerability to include coercion and undue influence.

SJSU Policy Recommendations

Compliance Date

Apply 2018 regulations to pre-2018 active protocols at the time that investigators submit an extension request. At that time, a continuing review will be conducted to determine whether the protocol needs to be revised in any way to accommodate the new regs; after this continuing review the investigator will no longer have to seek additional continuing reviews for protocols that underwent an expedited or exempt review.

Definition of Research

- Continue to include the definition of research, but add these examples to others already included in the policy (needs assessment, program evaluation, quality control, SJSU employee consultants, student classroom work intended as research practicum).
- Omit current reference that equates publication with generalizable knowledge.

Exempt Research

- Revise exemption categories accordingly.

- Apply the exemption categories to pregnant women (subpart B) and prisoners (subpart C) in the same way as the revised common rule does.

- Remove publication as a condition for not exempting research involving minors and apply exemption categories to minors (subpart D) in the same way as the revised common rule does. (See Section VI.C.1b of current SJSU policy).

- Merge the revised common rule concept of "limited IRB review" and the current SJSU policy of "IRB registration" for exempt research. Conduct an administrative review of all research qualifying for exemption that takes into consideration privacy and confidentiality protections and consent procedures (when applicable). The administrative review can be conducted by a qualified staff person. In cases where the work is also subject to a limited IRB review under the revised common rule, the review can be conducted by a qualified staff person or through an expedited review by an IRB member.

- Add language to the policy that all research proposals, regardless of whether they qualify for exemption, must be 1) complete, 2) written in a manner that is comprehensible to a general audience, and 3) apply relevant professional standards and best practices, including the minimization of risk to participants and a plan to mitigate conflicts of interests or situations that present undue influence.

- Continue to require some form of consent for applicable exempt research. For research involving minors, whether exempt or not, require written parental consent except if participants are college students and are providing consent for their participation in school-based research. For exempt research involving adults only, require consent notice but not signed consent, except when other policies require participant written authorization (e.g., FERPA, HIPAA). The Office of Research will provide templates for all required consent documents, including the standard consent form for adults, parental authorization form, consent notice, and broad consent form.

Refer to the Table of Exemption Categories for a list of the exemption categories under the revised rule, info on how the exemptions apply to the subparts under the revised common rule, and my recommendations on how consent should be applied under SJSU policy:
http://www.sjsu.edu/research/docs/2018-Table-Exemption-Categories.pdf

Continuing Review

• Revise continuing review requirements accordingly. (Only full review protocols require continuing review unless justification is provided for continuing review of specific expedited protocols).

• Discontinue practice of requiring extensions for exempt research, but continue to require modification requests for exempt research.

• If a paper submission process is still in place at the time that the new rules are implemented, investigators should be required to submit a report indicating their study is complete.

Single IRB Mandate

• Add to policy accordingly.

• The Office of Research will use a reliance agreement for collaborative research.

• Registration of non-collaborative research for outside investigators coming to SJSU where SJSU is not engaged in the research.

• Add policy that the SJSU IRB will not review protocols from investigators that come from institutions lacking an IRB.

Consent

• Revise policy accordingly; our policies and procedures already fulfill most of the requirements, so only minor additions need to be made. However, the broad consent option needs to be added to the available templates and guidance needs to be provided on when broad consent is applicable.

• Continue to require some form of consent for applicable exempt research. For research involving minors, whether exempt or not, require written parental consent except if participants are college students and are providing consent for their participation in school-based research. For exempt research involving adults only, require consent notice but not signed consent, except when other policies require participant written authorization (e.g., FERPA, HIPAA).

• Federal regs contain no recommendations regarding assent, but I propose to add to the SJSU policy: Assent is required in cases where obtaining assent is appropriate for the age and developmental ability of the target population regardless of whether the protocol undergoes an administrative review or an IRB review. PIs are required to provide an explanation of how assent will be obtained or a justification for why it would not be appropriate to obtain assent in a specific case.

• Remove specific reference in SJSU policy that provides additional safeguards to "individuals institutionalized as mentally disabled" and replace with "individuals with impaired decision making ability; individuals who may be susceptible to coercion or undue influence because of a power imbalance in their relationship with the investigator; or any other potentially vulnerable groups."

Other SJSU Policy Recommendations (not related to revised common rule)

• Update our office name throughout.
• Update membership and personnel info in Section VI.A.4.
• Add training requirement for IRB members.
• Update the number of years that members are appointed according to recent SJSU policy changes (Section II.A.3 and Section VI.A.1). Also add voting status of IRB analyst and IRB member selection process as indicated by the recent F15-8 policy modification.
• Omit reference to registering non-research activities with our office (Section III B.1).
• Clean-up and clarify section on student classroom activities. Keep that it should be minimal risk and not target special populations or sensitive subject matter, but omit listing of examples that might exceed the minimal risk standard. Also refer to student classroom work as research practicum and not research (Section IV.C).
• Expedited review categories need to be updated to reflect current list provided by DHHS, (Section VI.C.2f).
• Remove requirement to submit two paper copies – this is a procedural requirement and does not belong in the policy (Section VI.B.2).
• Remove reference to University letterhead. It's sufficient to state electronically.
• Update appeal procedures to include appeals to revision requests conducted under administrative review – such appeals requests should go to the IRB chair (Section VI. D. 5 and 6).
• Clarify that appeal should first go to the chair; if chair does not grant appeal, then it goes to full committee.
• Add that an administrative review by a qualified IRB staff member can take place for protocol modifications unless the modifications increase the risk to subjects.
• With the exception of defining "minimal risk," omit all other descriptions of risk from current policy (psychological, social, group risk). This is educational info and not policy info, and it is not an exhaustive list.
• Add adverse event reporting procedures - this is required!
• Add that IRB and Office of Research has the authority to audit research records and activities.
• Remove inconsistencies, language that appears to violate the common rule, and re-organize and simplify the presentation of information to avoid redundancy and confusion. Refer to a previous document "2008 SJSU HSR Policy Proposed Revisions" (link below) that I created in 2014 that outlines these problems. The new policy may be ordered differently due to the revised common rule and to reduce the redundancy and confusing organization of the current policy. Wherever possible, reference should be made to the revised common rule directly (with hyperlinks) to orient readers to further information.

2008 SJSU HSR Policy Proposed Revisions: http://www.sjsu.edu/research/docs/2008-SJSU-HSR-Policy-Proposed-Revisions.pdf

Rationale for Recommendations

Compliance Date

Having all active protocols comply with the new regulations ensures consistency and reduces the administrative burden of having to apply two sets of standards to different protocols. Having the investigator make any necessary revisions to comply with the new rules at the time of the extension request minimizes the burden on investigators while alerting them to the change in policy.

Definition of Research

Adding examples of activities excluded from the definition of research serves to provide greater clarification and is not a policy change per se. The guidance accompanying the new regs provides a justification for explicitly excluding journalism and oral histories as follows:
"In these activities the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not necessarily to protect them from public scrutiny." However the guidance does distinguish journalism and oral histories from ethnography, stating "studies using participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research of the final rule." The guidance also explains why public health surveillance activities and criminal and national security investigations don't fall within the scope of the final rule, but these types of activities are not typical for SJSU and our policy does not require further elaboration on these points.

Exempt Research

• These recommendations would further harmonize SJSU policy with the federal regulations without significantly impacting protections for human subjects.

• Currently, SJSU applies a different standard for research involving minors that would be exempt under the federal regulations. We require that research involving minors, despite qualifying for exemption, should go through an IRB review if the work is to be published. Since the intent to publish is not always known at the outset of the work, is not a measure of whether an activity meets the definition of research, and does not mean that risks to subjects have been minimized if the work ends up not being published, the criteria for applying exempt status to research with minors should not rest on publication. Research that qualifies for exemption is inherently minimal risk. SJSU can best protect minors, not by requiring an IRB review when the work qualifies for exemption, but by continuing to apply more stringent consent requirements for work involving minors. Having research with minors that qualifies for exemption undergo an administrative review by a qualified staff member, rather than undergoing an IRB review, increases efficiency.

• The concept of "limited IRB review" introduced by the revised regulations is synonymous with our current process of IRB registration for exempt research but allows for the option of having an exempt protocol be reviewed by either a qualified IRB member or a qualified staff member. Since this new aspect of the regulations is already being practiced, it does not represent a significant policy change but serves to clarify the circumstances under which limited IRB review will take place and what the criteria for review will be.

• Adding language to the policy requiring a basic quality standard for research protocols emphasizes the obligations of researchers and provides a rationale for returning protocols to investigators for further revisions if they do not meet the basic standards of completeness and comprehensibility.

• Continuing to require some type of consent for exempt research upholds the current SJSU policy but provides clarification for some specific situations (e.g., minors, other applicable regulations). Since most situations for exempt research will involve consent in the form of a written informational notice, upholding this requirement does not pose additional burdens for researchers and enhances protections for research participants. To avoid confusion, the consent process for exempt research can be referred to as "consent notice" or simply "notice" to distinguish it from the "consent form" typically required for non-exempt research.

To read a discussion, analysis of public comments, and justification of the new exemption categories, please refer to pages 7186 to 7200 of the preamble to the revised common rule available at: https://www.federalregister.gov/documents/2017/01/19/2017-010

Continuing Review

• In practice, requiring continuing review for expedited and exempt research has proven not to serve any practical purpose and does not enhance protections for subjects. Most investigators submit modification requests throughout the year and have little to report at the one year anniversary of their IRB approval. Investigators should continue to submit modification requests throughout the course of their research activity and get approval for modifications prior to initiating them. Maintaining a robust and efficient modification approval system does more to protect subjects than conducting annual reviews of protocols.

• Having investigators submit a study completion report enables the Office of Research to have information on which protocols are active. Since we are required to retain IRB records for 3 years after study completion, this enables accurate maintenance of paper files. If we have an electronic submission system, this may no longer be required because in practice the files are kept indefinitely, but for paper files we only have a limited amount of space.

Single IRB Mandate

Adding policy language about the single IRB mandate serves only to verbalize what has already been a practice. Requiring investigators to obtain IRB approval from multiple institutions is inefficient and duplicates work unnecessarily. However, adding language stating the SJSU IRB will not review protocols from investigators that come from institutions lacking an IRB is a new policy suggestion meant to protect the SJSU IRB from legal liability. The revised regulations now hold the reviewing IRB accountable rather than the institution where the research is conducted if the review is inadequate. The SJSU IRB should be protected from the legal ramifications of this shift in policy. Since IRB members, apart from the chair, are not compensated for their work, this also reduces the burden on the IRB to provide a service for researchers who are not part of the SJSU community. The implication of this policy will be that external investigators cannot conduct research on this campus if the don't already have IRB approval.

On the other hand, researchers who do have IRB approval from elsewhere need not have the review conducted by an IRB with federal wide assurance (FWA), since the reviewing IRB is held accountable regardless. If the investigator needs documentation from our office that we have been made aware of the research, the registration will fulfill this need, while keeping SJSU in the loop about the research activities if we are called upon to provide documentation of an outside investigator's compliance or if a subject at SJSU is injured.

Consent

• Continuing to require some type of consent for exempt research upholds the current SJSU policy but provides clarification for some specific situations (e.g., minors as subjects, other applicable regulations). Since most situations for exempt research will involve consent in the form of a written informational notice, upholding this requirement does not pose additional burdens for researchers and enhances protections for research participants. To avoid confusion, the consent process for exempt research can be referred to as "consent notice" or simply "notice" to distinguish it from the "consent form" typically required for non-exempt research.

• In social, behavioral, and educational research of the kind conducted by most SJSU investigators, the wishes of the child typically outweigh those of the parent if the child does not wish to participate in the research. For this reason, seeking assent from minors who are capable of making an informed decision is more appropriate than it may be for clinical research where the minor stands to directly benefit from the medical intervention. Adding language about assent to SJSU policy acknowledges that the degree to which minors are capable of autonomy should be respected. Because the way in which assent may be pursued (e.g., verbal, written) will depend on the age, developmental ability, and maturity of the minor, the policy should not establish any specific requirements for how assent is obtained and it should allow for investigators to provide a justification for requesting a waiver.

• There is no reason to provide additional protections to "individuals institutionalized as mentally disabled" over any other vulnerable group. Individuals who are institutionalized tend to have a legally authorized representative (LAR), which typically makes the consent process easier than those individuals who don't have a LAR but may have an impaired decision making ability. The revised language emphasizes the fact that the level of vulnerability of a subject is often tied to the ability to give consent, and at the same time the revised language does not focus on or stigmatize a specific group (e.g., the "institutionalized").

Other SJSU Policy Recommendations (not related to revised common rule) These recommendations seek to clarify the existing SJSU HSR policy and tomake it more accessible, readable, consistent, and current with the new regulations.